

# The Supply of Pharmaceuticals in Humanitarian Assistance Missions: Implications for Military Operations

Maysaa Mahmood, PhD\*; Kevin Riley, PhD\*; David Bennett, PhD†; Warner Anderson, MD‡

**ABSTRACT** In this article, we provide an overview of key international guidelines governing the supply of pharmaceuticals during disasters and complex emergencies. We review the World Health Organization's guidelines on pharmaceutical supply chain management and highlight their relevance for military humanitarian assistance missions. Given the important role of pharmaceuticals in addressing population health needs during humanitarian emergencies, a good understanding of how pharmaceuticals are supplied at the local level in different countries can help military health personnel identify the most appropriate supply options. Familiarity with international guidelines involved in cross-border movement of pharmaceuticals can improve the ability of military personnel to communicate more effectively with other actors involved in humanitarian and development spheres.

Enhancing the knowledge base available to military personnel in terms of existing supply models and funding procedures can improve the effectiveness of humanitarian military operations and invite policy changes necessary to establish more flexible acquisition and funding regulations.

## INTRODUCTION

Maintaining a consistent supply of essential medicines is a life-saving aspect of humanitarian assistance (HA) missions. A good understanding of the international guidelines governing the supply of pharmaceuticals in different countries is key to ensuring the availability of adequate quantities of quality medicines when responding to humanitarian needs.

In compliance with existing laws and regulations, current and past military HA missions have attempted to meet U.S. standards of care and relied almost exclusively on Department of Defense (DoD) supply channels to provide pharmaceuticals that are approved by the Food and Drug Administration (FDA) in support of these missions.<sup>1</sup> Regardless of the legal authority under which a military HA mission is conducted, federal acquisition regulations (FARs) mandate that all purchased pharmaceuticals be approved by the FDA, the federal entity designated to provide quality assurance support for acquisitions of drugs, biologics, and other medical supplies.<sup>2,3</sup> The FARs also mandate that pharmaceuticals be purchased from approved General Services Administration (GSA) vendors or U.S. civilian suppliers through U.S. military channels. Exceptions can be made to allow for the purchase of pharmaceutical products from alternative sources when there is reasonable justification (such as lower product cost, lower shipping cost, and in the case of medicines that are not available from U.S. sources), as well as evidence to show that these products meet international quality standards.

The recent types of missions undertaken by DoD, however, highlight a need for more flexible funding and acquisition arrangements to provide pharmaceutical support in response to humanitarian needs. Military personnel have come to realize the need to provide pharmaceutical assistance in a manner that addresses the actual needs and capacity of the host country. Understanding how pharmaceuticals are supplied at the local level, in terms of the types of medicines used, sources of supply, price structure, distribution channels, and government regulations, is key to providing pharmaceutical support that can be locally sustained once the U.S. military leaves.

This article provides an overview of key international guidelines governing the supply of pharmaceuticals during humanitarian emergencies. The goal is to help U.S. military service members gain a better understanding of existing supply models to facilitate more successful and efficient planning and execution of future HA missions. It highlights best practices (Table I) that have been established by leading civilian organizations to streamline the supply of pharmaceuticals during disasters and complex emergencies and invites changes at the policy level to establish more flexible funding and acquisition regulations that effectively address the new requirements for military HA missions.

## PHARMACEUTICAL POLICIES AND THE SUPPLY OF ESSENTIAL MEDICINES

The common practice in predeployment planning for HA missions is to conduct site surveys to gain a contextual understanding of existing healthcare infrastructure including commonly prescribed medicines.<sup>1</sup> Familiarity with host country's pharmaceutical policies can further enhance the effectiveness of predeployment planning and contribute to the overall success of the mission.

Most countries have a national formulary or a standardized essential medicines list (EML), which provides information

\*Center for Disaster and Humanitarian Assistance Medicine, Uniformed Services University of the Health Sciences, 11300 Rockville Pike, Suite 707, Rockville, MD 20852.

†College of Pharmacy, Ferris State University, 220 Ferris Drive, Big Rapids, MI 49307.

‡International Health Division, Office of the Assistant Secretary of Defense (Health Affairs), Force Health Protection and Readiness, 5113 Leesburg Pike, Suite 800A, Falls Church, VA 22041.

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**TABLE I.** Relevant Reference Documents and Websites

National Lists of Medicines/Formularies
World Health Organization Medicines Publications and Documentation <a href="http://apps.who.int/medicinedocs/en/">http://apps.who.int/medicinedocs/en/</a>
World Health Organization Essential Medicines Library <a href="http://apps.who.int/emlib/">http://apps.who.int/emlib/</a>
Pharmaceutical Procurement
World Health Organization Operational Principles for Good Pharmaceutical Procurement <a href="http://www.who.int/3by5/en/who-edm-par-99-5.pdf">http://www.who.int/3by5/en/who-edm-par-99-5.pdf</a>
World Health Organization Interagency Emergency Health Kit (2006) <a href="http://apps.who.int/medicinedocs/pdf/s13486e/s13486e.pdf">http://apps.who.int/medicinedocs/pdf/s13486e/s13486e.pdf</a>
Pharmaceutical Quality Assurance
World Health Organization Guidelines for Drug Donations (1999) <a href="http://whqlibdoc.who.int/hq/1999/who_edm_par_99.4.pdf">http://whqlibdoc.who.int/hq/1999/who_edm_par_99.4.pdf</a>
World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce <a href="http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/">http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/</a>
World Health Organization International Pharmacopeia <a href="http://www.who.int/medicines/publications/pharmacopoeia/en/index.html">http://www.who.int/medicines/publications/pharmacopoeia/en/index.html</a>
Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide—United States Pharmacopeia <a href="http://www.usp.org/pdf/EN/dqi/ensuringQualityOperationalGuide.pdf">http://www.usp.org/pdf/EN/dqi/ensuringQualityOperationalGuide.pdf</a>

about available medicines that are relevant to the treatment of diseases prevalent in a particular country.<sup>4</sup> The World Health Organization (WHO) introduced the concept of the EML to encourage health systems at the country level to focus on a limited number of carefully selected medicines for which evidence exists to ensure efficacy, safety, and quality. It is an effective tool that can help countries manage the supply of pharmaceuticals more effectively and lower overall healthcare costs.<sup>4</sup> The WHO publishes a model list that is constantly updated and can be used as a global standard to guide country authorities develop their own national EMLs.<sup>5</sup>

In many developing countries, national formularies or EMLs guide the procurement process in the public sector, the acceptance of pharmaceutical donations during emergencies, and training of healthcare professionals on rational use of medicines.<sup>6</sup> As a result, many international organizations and nongovernmental organizations (NGOs) involved in HA and health sector development base their pharmaceutical supply system on the EML concept. This assures smooth integration into the host country's system, with less waste and better sustainability.

Military personnel who have a basic understanding of the country's essential medicines policies and procedures before deployment can communicate more effectively with other actors providing services at the local level and identify available opportunities to coordinate efforts. Such understanding can also help planners make well-informed selection, acquisition, and distribution decisions to ensure continuity of care, sustainability of services, and benefits to the local population. Information about a country's pharmaceutical policies and

EML can usually be obtained from one or more of the following sources:

- The country's national health authority (Ministry of Health) websites or contacts
- The WHO Medicines Publications and Documentation Library<sup>7</sup>
- NGOs with ongoing health activities in the country

## **GUIDELINES FOR DRUG DONATIONS**

Drug donations play a vital role in addressing humanitarian needs during emergencies. However, for the benefits of these donations to be realized, they need to be provided in accordance with national and international guidelines and actual needs at the country level. Many countries impacted by disasters and other emergencies often report receiving inappropriate drug donations in the form of irrelevant or expired drugs.<sup>8</sup> The uncontrolled influx of inappropriate drug donations can create a serious and unnecessary burden as many of these countries struggle with the waste, confusion, and the additional costs incurred from handling these donations. Every donation requires storage space, security and manpower, as well as destruction cost for unused medicines.<sup>9</sup>

To address the numerous problems associated with inappropriate drug donations, the WHO has published guidelines that streamline the process of donating pharmaceuticals.<sup>10</sup> Although not legally binding, these guidelines are internationally recognized and are applicable to drug donations made in emergency situations and as part of developmental aid. The WHO guidelines for drug donations are endorsed by the United States Agency for International Development (USAID) and provide the basis for approving requests to transport pharmaceuticals donated by NGOs, international organizations, and other private voluntary organizations on U.S. military cargo aircraft and vessels.<sup>11</sup>

The guidelines include 12 articles that are based on 4 core principles; maximizing the benefit to recipient countries, respecting their wishes and authority, avoiding double standards in terms of quality, and ensuring effective communication between donor and recipient countries. To ensure maximum benefit, donors need to make sure that drug donations are relevant to the emergency situation and are based on an expressed need. Donated drugs should be approved for use in the recipient country and listed on their national EML. In case a national EML is not available, it is recommended to use the WHO Model EML to make sure that only essential medicines are sent.

The quality of donated medicines is a primary focus of the WHO guidelines. All donated pharmaceuticals should be obtained from reliable sources, comply with quality standards in both the donor and the recipient countries, and have a remaining shelf life of at least 1 year after arriving in the recipient country. Regulatory agencies around the world prohibit the donation of drugs that are expired or near their expiration date as these are considered adulterated products. Once

the expiration date has passed, there is no assurance that these drugs have the identity, safety, strength, quality, and purity characteristics they claim to possess.<sup>12–14</sup> Expiration dates tend also to be impacted by the climate in the recipient country; elevated temperature and high humidity can increase the rates of drug decomposition and reduce the original shelf life of donated products.<sup>15</sup>

The Sri Lankan experience with post-tsunami pharmaceutical assistance can illustrate how inappropriate drug donation can hinder, rather than assist, disaster relief effort and highlight the importance of adhering to WHO guidelines for drug donations.<sup>9</sup> According to the Sri Lankan Medical Supplies Division, more than 3500 truckloads of drug donations were received in Sri Lanka during the 5 months after the tsunami. Unprecedented quantities of medications flowed into the country, many of which had not been registered in the country before. Data from the Pharmacology Department at the University of Colombo showed that only 60% of donated drugs were registered in Sri Lanka, 10% were on the Ministry of Health's expressed list of medications needed, 50% had expiration dates printed on the package, 5% either expired on arrival or within a few days of arrival, and approximately 62% were labeled in a language other than English, the language read and understood by most health professionals in Sri Lanka.

The burden placed on the Sri Lankan government as a result of these inappropriate drug donations was significant. A year after the tsunami, unused drug donations were found in hospitals and clinics across the country and approximately 25% of the donations needed to be destroyed for a variety of reasons, including past expiration dates, labels in unknown languages, and excessive quantities. The indirect cost associated with the inappropriate donations was also considerable. The continued presence of expensive foreign pharmaceuticals, usually never registered in Sri Lanka, not only resulted in the disruption of the local pharmaceutical market, but was also altering prescribing patterns of local physicians.

The Sri Lankan experience with inappropriate drug donations is not unique; in Bosnia and Herzegovina, an evaluation of the appropriateness of donated medical supplies found an estimated 17,000 metric tons of inappropriate medicines stockpiled in clinics and hospitals. The evaluation estimated that for each ton of inappropriate drugs donated, donors were probably avoiding destruction costs of approximately \$2,000, and were putting the recipient country in the position of having to destroy these drugs at a significant cost. Thus, in the case of Bosnia and Herzegovina, 17,000 metric tons of inappropriate drugs might have saved donors \$25.5 million (after the deduction of \$500 per ton for the cost of transportation) and cost the recipient country approximately \$34 million.<sup>16</sup>

## **PHARMACEUTICAL QUALITY ASSURANCE CAPACITY AT THE COUNTRY LEVEL**

The primary goal of providing pharmaceutical assistance as part of a long-term developmental aid is to build local

capacity for pharmaceutical supply chain management at the country level. While trying to assist the Afghan National Security Forces (ANSF) health system to procure pharmaceutical products, the Combined Security Transitions Command-Afghanistan (CSTC-A) struggled with a number of challenges (name withheld, personal communication). The high prevalence of poor quality pharmaceutical products and the lack of a functional health authority to regulate the pharmaceutical market and guarantee quality of available products in Afghanistan are among the main challenges that many donors and aid organizations continue to struggle with (M. Morris, personal communication), including CSTC-A.

In many developing countries, where financial resources and technical expertise are not available to establish a national quality assurance system, alternative resources such as the WHO Certification Scheme on Quality Pharmaceutical Products can be used.<sup>17</sup> The WHO scheme allows countries with no quality control capacity or in which existing capacity is hindered by an emergency situation to import pharmaceutical products or accept donations with some degree of quality assurance.

The WHO scheme is an administrative tool based on internationally recognized quality assurance standards that can assist countries receiving pharmaceutical products in getting formal assurance about the registration status and the quality of medicines entering the country. Similar to the WHO guidelines on drug donations, the scheme has no legal status and is a nonbinding guideline. Two types of documents that satisfy the requirements specified under the WHO scheme are issued by the proper certifying authority in the exporting country. The first is the Certificate of Pharmaceutical Product, which is designed to provide the country importing drugs or accepting donations pertinent information about each product. The second is the Batch Certificate, which is issued by the manufacturer, and only exceptionally, as in the case of vaccines and other biological products, is issued by the competent authority of the exporting country. The certificate provides verification of the quality and expiration date of a specific batch of a product that has already been licensed in the recipient country.

The WHO scheme should not be considered as an absolute assurance of pharmaceutical product quality, it only guarantees that the product comes from reputable sources. It is important to remember that the two documents issued as part of this scheme are only as reliable as the regulatory authority that issues them in the exporting country.<sup>18</sup>

The use of the WHO scheme to ensure the quality of medicines in resources-limited environments illustrates the adaptive approach many organizations with long standing humanitarian and development engagement are taking to meet the actual need and capacity at the country level. Some international organizations have also established criteria to prequalify manufacturers, suppliers, pharmaceutical products, and regional quality assurance laboratories to improve the responsiveness, flexibility, and efficiency of the pharmaceutical supply chain during humanitarian emergencies while ensuring good quality and safe products.<sup>19</sup> For example, the WHO prequalifies



certain vaccines and manufacturers of medicines that treat HIV/AIDS, Malaria, and Tuberculosis to allow implementing organizations delivering healthcare services at the local level identify and procure products from reputable sources. The WHO also prequalifies regional laboratories for checking the quality of pharmaceutical products that can be used by countries that do not have access to their own regulatory testing laboratories.<sup>19</sup>

### **LOCAL PROCUREMENT OF PHARMACEUTICALS**

The benefits of procuring pharmaceuticals locally during HA missions need to be achieved in perspective of the overall goal of pharmaceutical assistance to provide equitable and affordable access to quality medicines. Although tempting, procuring pharmaceuticals locally in a country like Afghanistan, for example, can be very challenging. Afghanistan has limited local production capacity, and almost all pharmaceutical products available in the market are imported from countries with weak regulatory capacity and a reputation for poor quality controls in pharmaceutical production, like Pakistan, Iran, and China.<sup>20</sup>

Sound procurement decisions must be based on accurate and unbiased market information on product availability, product quality, comparative pricing, and supplier performance.<sup>21</sup> In many developing countries, especially those with limited regulatory capacity, this type of information is difficult to obtain.<sup>18</sup> Although it is almost always possible to get lower prices for medicines when purchased locally, lower product prices do not necessarily translate into lower total cost. Hidden costs associated with poor product quality, poor supplier performance, short shelf life, and other administrative procedures need to be considered as well.<sup>18</sup>

In Afghanistan, USAID attempted to tackle this issue and find an appropriate balance between price and quality by procuring pharmaceuticals through two preapproved international suppliers. USAID approved the purchase of restricted pharmaceutical products from foreign origin and relies on the supplier quality control mechanisms for selecting manufacturers that adhere to international quality standards. As part of the agreement with USAID, the suppliers ship their pharmaceutical products to Afghanistan with the required quality control documentation (P. Ickx, personal communication).

In 1999, the WHO published a document specifying a number of operational principles for good pharmaceutical procurement that can be used to guide the prequalification process of prospective suppliers. The WHO recommends using the following parameters to evaluate prospective suppliers: formal registration, formal inspection, reference checks with past clients and international agencies, and test purchases in small quantities. The purpose of prequalification process is to ensure that suppliers are properly registered and products are manufactured according to good manufacturing practices (GMP) and are approved in the country of origin.

In addition to the WHO, other organizations have also undertaken independent efforts to implement a pharmaceu-

tical supplier prequalification process including USAID, Pan American Health Organization (PAHO), and European Commission's Humanitarian Aid Department (ECHO). These organizations recognize that such measures are needed to avoid the inadvertent purchase of counterfeit or substandard/potentially dangerous medicines to meet urgent needs during HA missions.<sup>22</sup>

For countries that lack functional regulatory agencies and drug quality control capacity, the WHO recommends that they consider applying these principles and buy from suppliers that are known to provide quality products.

### **OPPORTUNITIES FOR CIVIL-MILITARY COORDINATION**

During humanitarian emergencies, both civilian and military entities employ a wide range of resources which might be unique to each. Humanitarian needs that arise during these emergencies often call for all actors to closely coordinate their efforts and pool their resources in a complementary way to ensure better and more effective service delivery.

The nature and level of interventions and assets needed during HA missions depend on the specific aspects of the emergency situation, including location, time, and severity.<sup>23</sup> For example, nonpermissive environments may constrain the ability of most civilian actors to take immediate action in response to urgent needs, and call for a more active involvement of the military.<sup>24</sup> On the other hand, complex emergencies usually unfold over an extended period of time and may involve activities beyond the scope of what the military is trained for or tasked to do. In such situations, the resources and extensive expertise of civilian actors are invaluable in addressing the needs of affected populations.

Coordination of military HA activities with other U.S. government agencies, NGOs, international organizations, and host country entities can maximize the value of available resources across the full spectrum of civilian and military assets. This can only be possible to the extent that all participating entities know each other, share information, identify and acknowledge their strengths, and explore available ways to collaborate with each other.

The military's unique logistical and airlift capabilities, for example, can be indispensable to civilian entities in emergencies that exceed or exhaust their capacity to respond effectively and in a timely manner. Within DoD, the Defense Security Cooperation Agency (DSCA) directs the funding and management of two programs that provide transportation of humanitarian supplies including pharmaceuticals on behalf of civilian agencies including NGOs, international organizations, and other U.S. government agencies; these are the funded transportation and the Denton space-available programs. Both programs are authorized under Title 10 U.S.C., Sections 2561 and 402.<sup>11,25,26</sup>

The funded transportation program authorizes DoD to transport HA goods within prescribed limits worldwide including the ability to pay transportation and other

associated administrative costs. The program is coadministered by the State Department, which receives requests from civilian entities and performs all the necessary inspection and certification of goods before forwarding to DSCA. The authority permits transportation via any mode and for any cargo that could be defined as humanitarian, with airlift usually reserved for emergencies.<sup>27</sup>

The Denton program allows DoD to transport privately donated humanitarian goods on a space-available basis. The State Department, USAID, and DSCA must certify that the material being transported meet prespecified criteria, that there is a legitimate need for it, and that adequate arrangements for distribution have been made.<sup>28</sup>

On the other hand, civilian humanitarian organizations, including international organizations, governmental organizations, and NGOs possess extensive experience, networks, and resources, which make them uniquely situated to respond effectively to different types of emergencies around the world.

The recent experiences of the U.S. military in Iraq and Afghanistan demonstrate that depending on the nature of the mission, success may hinge upon partnering with civilian agencies and capitalizing on their unique resources and expertise, specifically in cases where long-term capacity building activities are involved. In Afghanistan, for example, CSTC-A was challenged with the task of purchasing pharmaceuticals locally to supply ANSF facilities, an area where USAID has an extensive network of resources and expertise already in place. In Afghanistan, USAID oversees the supply of pharmaceuticals in 12 provinces to support healthcare services provided as part of its Basic Package of Health Services and Essential Package of Health Services. Additionally, it utilizes a drug supply management system operated by one of its implementing partners, Management Sciences for Health (MSH). MSH is responsible for procuring pharmaceuticals used by USAID contracted NGOs, and is the main organization assisting the Afghan Ministry of Public Health with the development of comprehensive pharmaceutical strategy and quality assurance program (M. Morris, personal communication). One of the available options for CSTC-A to deal with the issue of pharmaceutical procurement for the ANSF was to coordinate with USAID and its implementing partners to obtain relevant information about qualified suppliers and credible procurement sources.

Significant challenges remain, however, in the availability of consistent and reliable channels the military can use to coordinate with different civilian actors during humanitarian emergencies. Both military and civilian entities need policies and operational procedures that delineate different aspects of civil–military cooperation during humanitarian emergencies to help facilitate more effective communication and coordination.

## **CONCLUSION AND RECOMMENDATIONS**

As the landscape of DoD's global health engagement activities continues to change, with new policies being introduced

to authorize the U.S. military to conduct medical operations in support of local populations and health sector reconstruction, predeployment familiarity with existing models of health services delivery and medical supply channels in other countries becomes a necessity. Given the important role of pharmaceuticals in complementing most health services, a better understanding of how they are supplied and utilized in different parts of the world is instrumental to ensure that quality medicines are consistently available to support HA missions. Such knowledge can also facilitate better coordination of efforts between the U.S. military and other government agencies, international organizations, and NGOs, as it can enhance the military's awareness of, and sensitivity to, the culture of these organizations and how they conduct their operations.

The recent experiences of the U.S. military in Afghanistan and Iraq highlighted a number of challenges including a knowledge gap in terms of existing international regulations and models of pharmaceutical supply, as well as existing laws and funding authorization procedures to procure pharmaceuticals in support of HA missions. Enhancing the knowledge base available to military medical personnel to make them aware of potential alternative venues for pharmaceutical supply at the local and regional level is one approach to address this challenge. This, however, needs to be matched by efforts at the policy level to establish more flexible regulations and funding authorization processes and create official channels that can be used by the military to share information and coordinate with different civilian actors.

The recent publication of DoD Instruction (6000.16)<sup>29</sup> is an indication that such efforts are already under way. The new instruction has officially introduced the concept of Medical Stability Operations and called for the military health system to be prepared to provide healthcare to indigenous population and engage in health sector reconstruction when necessary in support of stability operations. The instruction recognizes the dynamic environment and the multiplicity and diversity of actors involved during humanitarian emergencies and highlights the importance of civil–military coordination and partnership. It emphasizes the need to ensure that acquisition and funding regulations adequately respond to the requirements of future military medical operations, and explicitly calls for identifying best practices from other U.S. government agencies, multilateral institutions, and NGOs to inform policy development and change.

The identification of best practices in pharmaceutical supply management is a contribution to the ongoing efforts to reorient future military HA missions to achieve long-term and sustainable health benefits. The practices identified in this article have been developed specifically to respond to local needs and existing capacity and have the flexibility to adapt to different operational environments. Policy changes are critically needed to allow for their incorporation in the planning and execution of future military HA missions, and spur the development of responsive and flexible supply models to ensure the

availability of quality and cost-effective medicines in support of the U.S. military efforts to provide sustainable HA.

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